



PATENT
Attorney Docket No.: 64118.000044

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
Vincent Bryan <i>et al.</i>	:	Group Art Unit: 1173
Appln. No.: 08/944,234	:	
Filed: October 6, 1997	:	Examiner: Lien M. Ngo
For: DRILL HEAD FOR USE IN PLACING	:	
AN INTERVERTEBRAL DISC DEVICE	:	

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR PRE-APPEAL BRIEF CONFERENCE

Pursuant to the Pre-Appeal Brief Conference Pilot Program announced in the Official Gazette, Applicants hereby request a pre-appeal brief conference in the above-referenced case.

This application is appropriate for a pre-appeal brief conference. A brief history of this application and why applicants believe that an appeal will succeed are set forth below. This application was filed on October 6, 1997. Throughout the past eight years, various iterations of the claims have been rejected no less than seven (7) times. To date, a prima facie case of anticipation has yet to be set forth. Accordingly, rather than proceeding with an expensive appeal, applicants respectfully request that the Office either refine its position or indicate its intention to allow an appeal to proceed.

The amendment to the specification filed December 4, 2002 is objected to under 35 U.S.C. §132 because it allegedly introduces new matter into the disclosure. The added material which is alleged to lack support in the original application is as follows: the method of milling a vertebral body using the present invention drill head in paragraph [52], for example, "with a form cutter having at least one milling surface selected to create a predetermined surface contour

in one of the adjacent vertebral bodies as the form cutter is moved by drive means 24.”

Applicant respectfully submits, however, that Paragraph 52 of the specification is supported by col. 6, lines 56-65 of U.S. Patent No. 5,674,296 -- which was expressly incorporated by reference in the original specification -- and by Page 5, lines 7-18 of the original specification.

Claims 131, 134 and 137 have been rejected under 35 U.S.C. §112(b), first paragraph, as lacking support in the specification. Regarding claim 131, the Examiner alleges that it cannot be understood why a form cutter having a convex shape can prepare the bone to accept a concaval-convex shape of an endoprosthesis. Applicant respectfully submits that the specification clearly supports this recitation. *See, e.g.*, Paragraph 20 of the published original specification (“This convex surface 42 of the form cutter 29 functions to provide the bone of a vertebral body with a mating shape complementary to the concaval-convex shape of the endoprosthesis which is the subject of co-pending U.S. patent application Ser. No. 08/681,230 [now U.S. Patent No. 5,674,296].”)

Regarding claim 134, the Examiner alleges that “said form cutter has at least one vertebral body surface contour milling surface” is not supported in the specification. Applicant respectfully submits, however, that Figure 2 discloses a rotary form cutter 29 that has two distinct milling surfaces, an inner convex milling surface 42, surrounded by an outer concaval milling surface which terminates at peripheral edge 44, and thus shows a form cutter having at least one vertebral body surface contour milling surface 42 and 44. Regarding claim 137, the Examiner alleges that “said contour being generally parallel to said elongated shaft portion” is not supported in the specification. Applicants respectfully submit that Figure 2 depicts a drill head 20 having a form cutter portion 22 having a top-most point forming a tangential line that is parallel to the length of the elongated shaft portion 40.

On the merits, Claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128, 130-138 have been rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 4,197,645 to Scheicher. ("Scheicher"). That rejection is flawed for at least two reasons.

First, the Examiner's allegation that Scheicher is capable of performing like the claimed devices is incorrect as a matter of fact. The Examiner offers two techniques: (1) inserting the Scheicher drill heads *lengthwise* into the area between adjacent vertebral bodies (i.e., such that the drill heads are parallel to the surface of the adjacent vertebral bodies, and (2) drilling *through* a vertebral body to get into the area between adjacent vertebral bodies.¹

The parallel or lengthwise technique is illustrated in marked-up Figures 2 and 3 provided in Applicants' Response to Office Action of September 24, 2004. Figure 2, for example, shows the Scheicher drill heads entering the area between two adjacent vertebral bodies (depicted as mirror-image brackets "]" ["). Figure 2 indicates -- in the Examiner's handwriting -- that the space between the two brackets "would be the same space between two adjacent vertebral bodies." Thus, the drill heads are inserted *lengthwise* into the area between the adjacent vertebral bodies such that the sides of the drill heads are parallel to the surfaces of the vertebral bodies. As shown, milling is accomplished along the length of drill heads 5b and 5c.

The Examiner indicates that the distance between drill heads 5b and 5c comprises the claimed "height" of the form cutter profile. However, marked-up Figure 3 clearly shows that the distance referred to by the Examiner -- either A, B, or C -- is the distance between the *midpoint* of any two shafts supporting drill heads 5a, 5b or 5c, and *not*, as the Examiner submits, the *width*

¹ As part of its response to the Final Office Action of August 22, 2003, Applicants submitted the Declaration of Carlos Gil which sets forth, among other things, Mr. Gil's expert opinion that the Scheicher device is not capable of operating like the claimed devices.

of any two drill heads side-by-side. Applicants respectfully submit that such a distance would necessarily be greater than any of the distances A, B or C, thus bringing into question whether the drill heads of the Scheicher device: (1) are “capable of imparting a concaval-convex shape to the bone of vertebral bodies” as expressly recited in claim 1, or (2) could fit within the space defined by adjacent vertebral bodies “in order to create a surface contour in one of the adjacent vertebral bodies,” as recited in claim 25, for example.

The second technique proposed by the Examiner is also illustrated in Applicants’ Response to Office Action of September 24, 2004. In this technique, the Scheicher device is used to drill *through* one of the adjacent vertebral bodies (from top to bottom, for example) so that the drill heads may enter the space between adjacent bodies and eventually come into contact with the surface of the *other* vertebral body. According to the Examiner, it is irrelevant whether a live patient could survive or tolerate such a procedure, or whether such an approach is even possible on a live subject.² The Examiner asserts that the technique would result in the creation of a surface contour in one of the adjacent vertebral bodies, regardless of what happens to the live patient.

Applicants respectfully disagree that using the Scheicher device in either of the two techniques would prepare a space in a human spine to receive an insert between adjacent vertebral bodies and/or create a surface contour in one of the adjacent vertebral bodies. Moreover, Applicants respectfully submit that the function one desires to achieve dictates the structure that must be employed. Scheicher and the pending claimed devices are going after two distinct functions: the former a dental drill with elongated drill heads, and the latter a narrow

² Of course, if the preamble is given patentable weight -- which Applicants submit it must -- the effect on a live patient would be relevant.

form cutter that must fit in the narrow space between adjacent vertebral bodies. Applicants respectfully submit this fundamental distinction is properly set forth in each of the pending claims, and thus must be given patentable weight.

Second, Scheicher does not teach or suggest numerous recitations of the pending independent claims. For example, Applicant respectfully submits that independent claim 1 is structurally patentable over Scheicher because Scheicher does not teach or suggest a form cutter having "a profile . . . of a height capable of being admitted into the space between two opposing vertebral bodies." Scheicher fails to disclose numerous recitations of the other pending independent claims.

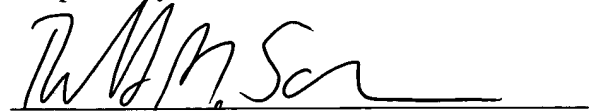
Other reasons why the anticipation rejection is flawed are set forth in detail in Applicants' Response to Office Action dated September 24, 2004 and Applicants' Response to Final Office Action Dated August 22, 2003. Consideration of each of these reasons is respectfully requested.

Thus, an appeal on the above bases will certainly succeed, but the time and expense in preparing an appeal brief on that issue should not be borne by Applicants when the grounds are so clearly improper.

Date: September 30, 2005

Hunton & Williams LLP
1900 K Street, NW
Washington, D.C. 20006-1109
Tel. (202) 955-1500 / Fax (202) 778-2201

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "R. M. Schulman", is written over a horizontal line.

Robert M. Schulman, Reg. No. 31,196